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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,888	08/27/1998	AGNETA PETTERSSON	1103326-0519	8291

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PATENT DEPARTMENT
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EXAMINER	
CHORBAJI, MONZER R	

20

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/125,888	PETTERSSON ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This non-final office action is in response to the RCE/Amendment received on 04/01/2003

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (U.S.P.N. 3,442,686) in view of Gordon et al (U.S.P.N. 3,967,728) and further in view of Lambert (U.S.P.N. 4,585,666).

With respect to claim 1; Jones discloses a method (examples 1-16) of using a laminate as a barrier material against gases (col.2, lines 4-7), the method includes a container, which is formed of a laminate (col.5, lines 45-63) having an inner polypropylene layer (col.4, line 20 and col.8, lines 63-64), an outer polyethylene terephthalate layer (col.4, lines 60-62, col.8, lines 20-21, and col.8, lines 65-66), and an intermediate silicon oxide layer (col.1, lines 17-19). In addition, Jones's laminate acts as a barrier when exposed to gases in general (col.1, lines 25-27 and col.2, lines 5-12). However, Jones fails to explicitly teach the specific type of gas such as ethylene oxide and also fails to teach the following: a package, which contains a medical instrument having a hydrophilic outer surface coating, a sealed container which contains a sterile wetting fluid for wetting the hydrophilic coating of the instrument, the laminate is substantially impermeable to ethylene oxide gas, and exposing the package to ethylene oxide gas. Gordon et al, which is in the art of packaging catheters discloses the following: a package (11), which contains a medical instrument (12), a sealed container (17) which contains a sterile wetting fluid for wetting the instrument, the laminate of the container is substantially impermeable to ethylene oxide gas (17 and col.3, lines 45-48), and exposing the package to ethylene oxide gas (11 and col.3, lines 36-44). Gordon et al fails to disclose a medical instrument having a hydrophobic outer surface coating. Lambert teaches a method for coating a medical instrument such that the outer surface

is hydrophilic (see example 1). Thus, it would have been obvious to one having ordinary skill in the art to modify Jones method to include a medical instrument having a hydrophilic outer surface coating, which has a low coefficient of friction when wetted with a water based liquid (Lambert, col.1, lines 7-11).

With respect to claims 2-4, Jones teaches the following: the polyolefin is polypropylene (col.4, line 20); the polyester for the outer layer of the laminate is polyethylene terephthalate (col.4, lines 60-62 and col.8, lines 20-21); the polyamide is nylon (col.4, line 26).

With respect to claim 5, Gordon et al discloses a urethral catheter for bladder drainage (12).

With respect to claims 6-10; Jones discloses an intermediate layer, which includes a layer of silicon and a polymeric matrix (col.2, lines 30-36, lines 55-59, col.4, lines 13-18, and col.6, lines 31-34). Furthermore, since all the various types of polymers in claims 7-9 have been shown to be disclosed as indicated above, the choice of such types in the construction of the matrix is well within the scope of a person having an ordinary skill in the art of designing laminates.

Response to Arguments

5. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

On page 4 of the response, applicant argues, "Jones does not disclose or suggest the use of the laminate as a barrier material in a medical package". Jones teaches that the laminate is to be used for packaging (col.1, line 13). Jones further

discloses that the laminate has an extremely low permeability to gases and liquids (col.2, lines 7-8). Thus, it would have been obvious to use the packaging material of Jones during ethylene oxide sterilization of Gordon et al. The Gordon reference only used to show ethylene oxide gas sterilization of catheters.

On page 4 of the response, applicant argues, "There is not teaching or suggestion whatsoever by Jones that the laminate is useful or suitable for medical applications". Jones teaches that the laminate has an extremely low permeability to gases (col.2, lines 7-8). Furthermore, Jones teaches the instant packaging film, which is capable of protecting objects from permeability from gas such that the use of ethylene oxide as a sterilant is known. Gordon et al discloses ethylene oxide as a sterilant. Thus, it would have been obvious to use the packaging material of Jones during ethylene oxide sterilization of Gordon et al.

On page 4 of the response, applicant argues, "there is no suggestion to one ordinary skill in the art to use the laminate as a barrier material in medical storage packages". Jones teaches that the laminate has an extremely low permeability to gases (col.2, lines 7-8). Gordon et al teaches that the package should have a gas impermeable laminate against ethylene oxide. Thus, it would have been obvious to use the packaging material of Jones during ethylene oxide sterilization of Gordon et al.

On page 5 of the response, applicant argues, "Gordon neither discloses nor suggests that materials other than metals could be successfully used as barrier materials. With specific reference to the claimed invention, there is especially no mention that inorganic oxides such as silicon oxide could be used successfully as a

barrier material". The Gordon et al reference used to show that ethylene oxide sterilization is known. The Gordon et al reference is not used for the laminate structure. Jones discloses the instant packaging film such that Jones packaging film has an extremely low permeability to gases (col.2, lines 7-8).

On page 6 of the response, applicant argues, "The examiner incorrectly states on page 4 of the office action that the barrier layer in figure 6 is made of Mylar (polyester). In fact, it is not the Mylar which provides the barrier properties, but the foil layer". Figure 6 in Gordon et al shows Mylar as the outer layer such that it is capable of acting as a barrier layer. Again, the Gordon et al reference is not used for the laminate structure. The instant packaging film is disclosed by Jones such that Jones packaging film has an extremely low permeability to gases (col.2, lines 7-8).

On page 6 of the response, applicant argues," Gordon discloses a catheter that is not pre-coated with a hydrophilic outer surface coating". The Lambert reference is used to show that it is known to pre-coat catheters with a hydrophilic outer surface coating (col.1, lines 7-11 and example 1).

Conclusion

6. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Matsuda et al (U.S.P.N. 5,725,958) disclosed laminates as a barrier material against gases used in the art of gas sterilization and Cameron (U.S.P.N. 5,135,501) discloses covering catheters with a hydrophilic outer surface coating.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
May 19, 2003

Robert J. Warden, Sr.

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